

EXHIBIT A

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**TAKEDA PHARMACEUTICAL
COMPANY LIMITED, et al.,**

Plaintiffs,

v.

**ZYDUS PHARMACEUTICALS USA,
INC., et al.,**

Defendants.

Civil Action No. 10-1723 (JAP)

**MEMORANDUM OPINION
FILED UNDER TEMPORARY SEAL**

This matter comes before the Court upon Plaintiff Takeda Pharmaceutical Company Limited's ("Takeda") Motion for Spoliation Sanctions in the form of exclusion of Zydus's evidence of particle size testing on pre-tableted granules. Defendant Zydus Pharmaceuticals USA, Inc.'s ("Zydus") opposes Takeda's motion. The Court has fully reviewed and considered all of the papers submitted in support of and in opposition to Takeda's motion and considers same without oral argument pursuant to FED. R. CIV. P. 78. For the reasons set forth more fully below, Takeda's Motion for Spoliation Sanctions is DENIED.

I. Background and Procedural History

The Court and the parties are very familiar with the facts underlying this matter. As such, the Court shall neither restate the facts of this case nor repeat the arguments made in support of and in opposition to Zydus's motion at length.

This is a patent infringement case dealing with United States Patent Nos. 5,464,632 (the "632 patent"), 6,328,994 (the "994 patent") and 7,431,942 (the "942 patent") and 7,875,292

(the “‘292 patent”) (collectively, the “patents-in-suit”).¹ The patents in suit cover Takeda’s Orally Disintegrating Tablet (“ODT”) formulation of the anti-ulcer drug, Prevacid®.

Zydus filed an Abbreviated New Drug Application (“ANDA”) with the FDA seeking approval to commercially market a generic lansoprazole ODT product (Zydus’s “ANDA product”). Takeda claims that Zydus’s ANDA product infringes upon all of the patents-in-suit and commenced this action on April 5, 2010 [Docket Entry No. 1].²

Zydus served its Non-Infringement and Invalidity Contentions on August 16, 2010. On December 3, 2010, Zydus served Amended Non-Infringement and Invalidity Contentions with the consent of Takeda and upon leave of the Court. A *Markman* hearing was held on May 26, 2011 and the Court issued its claim construction opinion on October 5, 2011 [Docket Entry No. 113]. Zydus’s Motion for Reconsideration of the Court’s ruling on claim construction was denied on January 25, 2012 [Docket Entry No. 130]. Fact discovery in this matter closed in December 2011 and expert discovery is ongoing. The parties are preparing for trial, which is tentatively set for August 13, 2012, and the 30 month stay will expire on August 19, 2012.

On January 17, 2012, the parties exchanged opening expert reports. REDACTED

REDACTED However, Takeda was only provided with samples of REDACTED during discovery and did not conduct testing on the REDACTED

REDACTED. As a result, Takeda filed this motion seeking to preclude REDACTED

¹The patents in suit are owned by Takeda with the exception of the ‘632 patent, which is licensed to Takeda by Ethypharm.

²The Original Complaint pertained only to the ‘994, ‘942 and ‘632 patents. The ‘292 patent, which is a continuation of the ‘994 and ‘942 patents, was added in Takeda’s First Amended Complaint on July 26, 2011 [Docket Entry No. 98] by consent of the parties.

REDACTED

II. Arguments

A. Takeda's Position

Takeda explains that, during discovery, it requested that Zydus produce samples of the REDACTED for Takeda's examination and testing. Zydus responded that it no longer possessed any samples and also refused to manufacture a new batch, alleging that such production would be costly. The parties exchanged some additional correspondence regarding this issue, but the record indicates that this was not a significant point of contention between the parties nor did either party seek the Court's assistance in resolving a dispute.

Takeda asserts that, upon receipt of Zydus's expert report, Takeda learned that Zydus's expert REDACTED

Takeda argues that it was prevented from performing any REDACTED which would enable it to rebut Zydus's tests and, as such, Takeda contends that it has been prejudiced. Takeda asserts that this litigation was foreseeable from the moment Zydus submitted its Paragraph IV Certification, therefore Zydus had an obligation to preserve the

REDACTED REDACTED
REDACTED Takeda states that Zydus's failure to preserve samples of its REDACTED is an inexcusable breach of its duty to preserve evidence and, as such, Takeda requests that Zydus be sanctioned for spoliation. Takeda suggests that the appropriate form of sanctions in this instance is exclusion of evidence of REDACTED

Takeda further states that, after receipt of Zydus's expert report, Takeda and Zydus met and conferred, at which point Takeda informed Zydus of its intent to file this motion. Shortly

thereafter, Takeda asserts that Zydus informed Takeda that it would be REDACTED and that Zydus would provide Takeda with samples of same. However, Takeda asserts that production of those samples is too late at this stage in the litigation and does not alleviate the harm caused by Zydus's spoliation of the original REDACTED. Takeda explains that the parties are close to trial and to the expiration of the 30 month stay. As such, Takeda contends that "[t]here is no time to spare for manufacture and receipt of REDACTED, reopened fact discovery to assess Zydus' manufacture, expert testing of the new REDACTED, preparation of a supplemental opening expert report on infringement by Takeda, followed by rebuttal reports and expert depositions." *Takeda's Memorandum in Support of Motion*, Docket Entry No. 146, *5.

B. Zydus's Response

Zydus has filed a responsive brief. In it, Zydus first argues that it has not destroyed any evidence or samples. Zydus explains that the REDACTED which it tested REDACTED, were utilized for their intended purpose and incorporated into the finished product. Zydus asserts that it provided Takeda with samples of the finished tablets into which the REDACTED were incorporated. Zydus also states that it provided Takeda with documents containing information about the manufacture and measurement of the REDACTED. Thus, Zydus asserts that it fully complied with discovery requests and that it is not guilty of spoliation.

Zydus argues that Takeda failed to pursue production of the REDACTED. Zydus points out that Takeda never sought to compel production of the REDACTED despite Takeda's knowledge that Zydus was capable of producing same, albeit at a significant

cost. Zydus suggests that Takeda did not seek the Court's assistance in compelling production of samples because Takeda feared that the Court would rule that Takeda pay the cost of production. In addition, Zydus asserts that, pursuant to Fed. R. Civ. P. 37, sanctions can only be issued upon a party's failure to comply with a court order. *Zydus's Memorandum in Opposition*, Docket Entry No. 156, *18. Zydus argues that here, Takeda never sought an Order from the Court therefore sanctions for spoliation would be inappropriate.

Zydus further asserts that Takeda is not prejudiced by its inability to perform testing on the REDACTED. Zydus explains that Takeda has “full access to the same materials REDACTED

REDACTED *Zydus’s Opposition* at *6; see also *Id.* at *15. Zydus states that its own expert REDACTED REDACTED; and instead she relied on the REDACTED

REDACTED Thus, Zydus concludes that Takeda is not prejudiced by the fact that its expert did not REDACTED

REDACTED. *Id.* at *21. Further, Zydus contends that Takeda will have an opportunity to depose Zydus’s expert and rebut her opinions.

[REDACTED]

[REDACTED]

[REDACTED] Zydus asserts that the timing was merely coincidental. Further, Zydus states that it will provide samples of the [REDACTED]

[REDACTED]

[REDACTED] Zydus contends that testing of the [REDACTED]

REDACTED will not take much time, thus, there is no reason why Takeda could not conduct the testing and include the results in either a revised opening expert report or a rebuttal expert report and then continue with expert depositions prior to trial. *Id.* at *25.

Zydus also argues that this litigation was not reasonably foreseeable due to the outcome of a similar case involving Takeda and another pharmaceutical company. Presumably, this argument goes to Zydus's assertion that they had no duty to preserve the REDACTED

Finally, Zydus responds to Takeda's comments regarding depositions of witnesses who were unable to obtain visas to enter the United States. These arguments have no bearing on the issue at hand; therefore, the Court will not address them in this Order.

C. Takeda's Reply

In its Reply Brief, Takeda asserts that Zydus's failure to preserve any REDACTED REDACTED, REDACTED, constitutes spoliation and has prejudiced Takeda. *Takeda's Reply Brief*, Docket Entry No. 160, *6. Takeda argues that documentation regarding Zydus's testing and measurement of the REDACTED is no substitute for the REDACTED themselves. Takeda contends that it "has the right to assess the very same samples that Zydus tested REDACTED" *Id.* Takeda explains that Zydus's choice to have REDACTED provided the impetus for this motion for spoliation. Takeda distinguishes the circumstances in this case from those in another case where this Court denied a similar motion for sanctions due to plaintiff's delay in filing same. *Schering Corp. v. Apotex Inc.*, No. 09-6373 (D.N.J. Mar. 7, 2012).

Takeda again explains its position that REDACTED

REDACTED Takeda requests that the Court reject Zydus's assertion that testing will take only a few days. Takeda contends that it "has the right to monitor the conditions under which Zydus' new batch are generated, collected, and measured in order to rebut any purported 'improvement' in the test results in Zydus' favor." *Takeda's Reply* at *8.

Takeda responds to Zydus's assertion that this litigation was not reasonably foreseeable and reminds the Court that "Paragraph IV Certifications and patent litigation go hand-in-hand." *Id.* at *9. Takeda cites a number of cases in support of this proposition. In addition, Takeda points out that Zydus's privilege logs, which contain specific claims to work product immunity, provide evidence that Zydus anticipated litigation with Takeda at the time Zydus conducted the REDACTED at issue. Takeda also points out that Zydus's REDACTED occurred before the Court's ruling in the *Teva Pharmaceuticals* case which Zydus cites in its brief. *Id.* at *11.

Takeda asserts that the Court can rely on its inherent authority, as well as the Federal Rules of Civil Procedure, to issue sanctions in this case. Takeda argues that a motion to compel is not requisite for sanctions in this instance because a motion to compel would not have brought back samples which were not available.

III. Analysis

A. Standard of Review

Spoliation is "the destruction or significant alteration of evidence, or the failure to

preserve property for another's use as evidence in pending or reasonably foreseeable litigation.” *Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422, 430 (S.D.N.Y. 2004) (internal quotation marks and citations omitted). It occurs “when a party has intentionally or negligently breached its duty to preserve potentially discoverable evidence[.]” *Kounelis v. Sherrer*, 529 F.Supp.2d 503, 518-519 (D.N.J. 2008). The duty to preserve evidence arises when a party reasonably believes that litigation is foreseeable and, as such, may arise “many years before litigation commences[.]” *Micron Technology, Inc. v. Rambus Inc.*, 255 F.R.D. 135, 148 (D.Del. 2009).

Evidence of spoliation may give rise to sanctions, which include: dismissal of a claim or granting judgment in favor of a prejudiced party; suppression of evidence; an adverse inference (i.e., the spoliation inference); fines; and attorney's fees.³ *Mosaid Tech., Inc. v. Samsung Elec. Co., Ltd.*, 348 F.Supp.2d 332, 335 (D.N.J. 2004). The imposition of sanctions is warranted “when there is evidence that a party's spoliation of evidence threatens the integrity of th[e] Court.” *Id.* Spoliation sanctions serve the following three functions: remedial, punitive and deterrent. They level the playing field so that the prejudiced party is restored to the position it would have been in absent the spoliation. They punish the spoliator for its misconduct and they warn other potential litigants that spoliation of evidence will not be tolerated and will be dealt with by the Court if necessary. *See Id.*

The Court has authority to impose spoliation sanctions pursuant to both the Federal Rules of Civil Procedure and its inherent authority, and the choice of which sanction should be imposed rests in the sound discretion of the Court. *Id.* Of the sanctions that can be imposed, dismissal

³The imposition of sanctions in patent cases is controlled by regional circuit law. *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1380 (Fed. Cir. 2004). Therefore the Court relies on Third Circuit law in analyzing what, if any, sanctions should be imposed on Roxane.

and suppression of evidence are considered the two most drastic and should only be levied in the most extraordinary of circumstances. *Id.* In determining whether such drastic sanctions are warranted, the Court considers: “(1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and (3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party and, where the offending party is seriously at fault, will serve to deter such conduct by others in the future.” *Schmid v. Milwaukee Elec. Tool Corp.*, 13 F.3d 76, 79 (3d Cir. 1994). In order to establish prejudice, the party seeking spoliation sanctions must “come forward with plausible, concrete suggestions as to what [the missing] evidence might have been (*Id.* at 80), and must show that its “ability to prepare effectively a full and complete trial strategy” has been impeded. *Ware v. Rodale Press, Inc.*, 322 F.3d 218, 222 (3d Cir. 2003). Generally, however, absent a showing of bad faith and substantial prejudice, dispositive sanctions should not be imposed. *See Schmid*, 13 F.3d at 80.

Of the lesser sanctions often considered by courts faced with spoliation is the spoliation inference. “The spoliation inference is an adverse inference that permits a jury to infer that ‘destroyed evidence might or would have been unfavorable to the position of the offending party.’” *Mosaid*, 348 F.Supp.2d at 336 (quoting *Scott*, 196 F.R.D. at 248). In order for the spoliation inference to apply, the party seeking the adverse inference must establish that the following four factors have been satisfied: “First, it is essential that the evidence in question be within the party’s control. Second, it must appear that there has been actual suppression or withholding of the evidence. Third, the evidence destroyed or withheld was relevant to claims or defenses. And fourth, it was reasonably foreseeable that the evidence would later be

discoverable.” *Mosaid*, 348 F.Supp.2d at 336 (internal quotation marks and citations omitted); see also *Aurelio v. Bd. of Educ. of the Borough of Carteret*, Civil Action No. 06-3146 (JLL), 2009 WL 1794800, *9 (D.N.J. June 23, 2009) (indicating that burden fell on Plaintiff, party seeking adverse inference, to show that all four factors were met)).

With respect to the second factor (i.e. “actual suppression”), “negligent destruction of relevant evidence can be sufficient to give rise to the spoliation inference.” *Id.* at 338. A party need not show that its adversary “*intentionally or knowingly* destroyed or withheld” evidence. *Id.* at 337. This is true because “[i]f a party has notice that evidence is relevant to an action, and either proceeds to destroy that evidence or allows it to be destroyed by failing to take reasonable precautions, common sense dictates that the party is more likely to have been threatened by the evidence” and, regardless of the “offending party’s culpability[,] . . . it cannot be denied that the opposing party has been prejudiced.” *Id.* at 338.⁴

In addition, with respect to the third factor, that the destroyed or withheld evidence is “relevant,” while not explicitly addressed by the Third Circuit or the District of New Jersey, typically, where the culpability of the offending party is negligence, gross negligence or even recklessness (as opposed to willful or knowing) the party seeking the spoliation inference must establish not only that the destroyed or withheld evidence is probative under Fed.R.Evid. 401, but also “must adduce sufficient evidence from which a reasonable trier of fact could infer that the destroyed or unavailable evidence would have been of the nature alleged by the party affected by its destruction.” *Zubulake*, 229 F.R.D. at 431, n. 67 (internal quotation marks and citation

⁴As described above, where one of the more drastic sanctions such as dismissal or suppression of evidence is sought, a greater showing of culpability may be required. *Schmid*, 13 F.3d at 80; see *Mosaid*, 348 F.Supp.2d at 338, n. 11.

omitted). In other words, the party seeking the spoliation inference must make a sufficient showing from which a fact finder could reasonably determine that the destroyed or withheld evidence would have been favorable to the movant.

B. Application

The Court finds that spoliation sanctions are not warranted for Zydus's failure to preserve samples of the REDACTED. Although it is unclear why Zydus failed to preserve these samples when it is evident that Zydus anticipated litigation in light of its Paragraph IV Certification and its specific claims to work product immunity in its privilege logs, the Court finds that Takeda was not prejudiced by this failure to preserve.

As set forth above, sanctions in the form of suppression of evidence, like the sanctions sought by Takeda in this motion, are considered drastic. *Mosaid Tech.*, 348 F.Supp.2d 332, 335. A factor in considering whether such drastic sanctions are warranted is the degree of prejudice to the opposing party. In order to establish prejudice, the party seeking spoliation sanctions must show that its "ability to prepare effectively a full and complete trial strategy" has been impeded. *Ware v. Rodale Press, Inc.*, 322 F.3d 218, 222 (3d Cir. 2003). In this case, Takeda has failed to meet that burden. Takeda may have been inconvenienced by Zydus's failure to preserve the samples in that Takeda would have had to file a motion to obtain the samples, nevertheless, the Court finds that the degree of prejudice to Zydus is minimal.

The Court agrees that Zydus should have preserved samples of the REDACTED for independent testing by Takeda. However, Zydus's failure to do so was an error which could have been remedied by the production of additional samples. Takeda could have achieved this result by motion practice during the discovery phase. Takeda is correct in its assertion that,

because no samples existed, a motion to compel production of existing samples would have been futile. However, Takeda had the option of seeking the Court's assistance in requiring Zydus to produce additional samples. It chose not to do so. As Takeda points out, REDACTED

Armed with this knowledge, Takeda could have sought to compel new samples for independent testing at any time throughout this litigation if it felt that such testing was necessary and critical to prepare its case. By opting not to pursue this avenue, Takeda indicated that testing of the REDACTED was not an element of its "complete trial strategy." Takeda cannot now feign surprise and claim prejudice because of Zydus's reliance on testing which had been previously cited and the documentation for which had been produced during discovery.

In addition, Takeda has access to the documentation regarding Zydus's original testing on the REDACTED and Takeda's experts can use that documentation to form their own opinions and formulations to rebut Zydus's expert. In addition, Takeda may address the significance of the lack of independent testing on the REDACTED at the time of trial through direct and cross examination of the experts. Further, Takeda now has the option to

REDACTED, assuming that such testing and accompanying expert reports can be produced within the confines of the controlling scheduling Order. For these reasons, there is no prejudice to Takeda.

The Court also takes issue with the timing of this motion. Takeda attempts to distinguish this case from the circumstances surrounding the Court's recent decision in *Schering*. *Schering*

Corp. v. Apotex Inc., No. 09-6373 (D.N.J. Mar. 7, 2012). Takeda focuses on the fact that it filed this motion promptly following the “triggering event,” which Takeda asserts was the presentation of Zydu’s expert report. However, as discussed above, the Court finds that Takeda was on notice since the time of t[REDACTED]

[REDACTED]. If independent testing on the [REDACTED] was a key element in Takeda’s argument for infringement, Takeda should have made an effort to obtain samples, and the proper time for seeking the Court’s assistance in this issue would have been during the discovery phase.

Matters of docket control and conduct of discovery are committed to the sound discretion of the Court. *In re Fine Paper Antitrust Litigation*, 685 F.2d 810 (C.A.Pa.1982). Also, the Court has broad discretion to control the method and timing of discovery. FED R. CIV. P. 26(b).

Given the nature of the case and the impact of the 30 month stay, which has been a significant factor in setting deadlines in this case, as well as a major impetus in the formulation of Local Patent Rules in general, Takeda’s delay in raising this issue is significant. In cases such as this, time certainly is of the essence. The parties are now mere months from trial and the expiration of the 30 month stay. Influencing the Court’s determination is the fact that this issue was not one over which the parties were engaged in the “meet and confer” process.

IV. Conclusion

For the reasons stated above, Takeda's Motion for Sanctions in the Form of Exclusion of Zydus's Evidence of Particle Size Testing on Pre-Tableted Granules is DENIED. An appropriate Order follows.

Dated: May 10, 2012

s/ Tonianne J. Bongiovanni
Tonianne J. Bongiovanni
United States Magistrate Judge